

Michio ISHIBASHI  
Attorney Docket No. 2005\_0275A  
Serial No. 10/527,216  
May 12, 2008

## REMARKS

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

### Claim Amendments

Claim 16 has been amended to delete “prevent” and “renal glomerular lesions”.

New claims 39-43 have been added to the application. Support for the new claims is found on page 40, lines 21-29, page 56, lines 25-26 and page 53, line 19 to page 54, line 2 of Applicant’s specification.

Thus, no new matter has been added to the application by the above-discussed amendments.

### Rejection Under 35 U.S.C. § 112, First Paragraph

The rejection of claim 16 under 35 U.S.C. § 112, first paragraph has been rendered moot in view of the above-discussed claim amendments.

The Examiner takes the position that the specification provides enablement for a method of screening a compound which is able to treat renal glomerular lesions, lesions of pancreatic islets of Langerhans or epidermal lesions, but does not provide enablement for a method of screening a compound which is able to prevent the aforementioned lesions. However, as discussed above, a method for screening a compound which is able to prevent the lesions was deleted from claim 16. Therefore, this rejection has been rendered moot.

Applicant notes that the Examiner’s rejection does not discuss the claimed method for screening a compound which is able to mitigate the recited lesions. In order to expedite prosecution, Applicant provides the following comments in this regard. Example 3 of Applicant’s specification (page 80), describes a compound which is able to mitigate the lesions. Compound (II-1), which induces regeneration-promoting CD11b<sup>+</sup>CD2<sup>+</sup> macrophages, diminished the excised wound area and crush formation of

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the complete skin-excised model rat. Thus, compound (II-1) mitigated and treated the skin lesion. In addition, the mitigation, i.e. palliative therapy, is included in the scope of treatment in the field, as shown in lines 1-2 of the abstract of the attached reference (Archer et al., "Palliative Chemotherapy: No Longer a Contradiction in Terms", The Oncologist, 1999, Vol. 4, pages 470-477). Therefore, the specification provides enablement for the method of screening a compound which is able to mitigate the lesions (as discussed above) and to treat the lesions (as discussed by the Examiner).

### **Patentability Arguments**

The patentability of the present invention over the disclosure of the reference relied upon by the Examiner in rejecting the claim will be apparent upon consideration of the following remarks.

### **Rejection Under 35 U.S.C. § 102(b)**

The rejection of claim 16 under 35 U.S.C. § 102(b) as being anticipated by Ishibashi et al. (EP 12777747) is respectfully traversed.

### **The Examiner's Position**

The Examiner takes the position that Ishibashi et al. disclose an invention that relates to a screening method for compounds that selectively suppress effector macrophages involved in progressive lesions without inhibiting the function and regeneration process of the organ. The Examiner further states that the method of screening a compound is characterized by the showing of less production of spontaneous plaque forming cell. Further, the Examiner states that the promoting action of suppression of compound 4-2 was shown to reduce glomerular lesion cases by 50%.

Applicant's Arguments

As discussed above, a method for screening a compound which is able to mitigate or treat renal glomerular lesions has been deleted from the scope of independent claim 16. Ishibashi et al. neither disclose nor suggest a method for screening a compound capable of mitigating or treating lesions of pancreatic islets of Langerhans or epidermal lesions. Lesions of pancreatic islets of Langerhans and epidermal lesions are entirely different from glomerular lesions. Therefore, the invention of independent claim 16, as well as the inventions of dependent claims 39-43 are clearly patentable over the teachings of Ishibashi et al.

Additionally, the cited reference fails to teach or suggest the more specific method recited in claim 42. Specifically, the cited reference fails to teach or suggest a method comprising inducing regeneration-promoting CD11b<sup>+</sup>CD2<sup>+</sup> macrophages and regulatory CD2<sup>-</sup>CD4<sup>+</sup> T lymphocytes by cultivating human peripheral blood mononuclear leukocytes in a medium in the presence of the test compound, lipopolysaccharide and human AB type serum, measuring numbers of CD11b<sup>+</sup>CD2<sup>+</sup> macrophages and regulatory CD2<sup>-</sup>CD4<sup>+</sup> T lymphocytes, comparing the numbers with numbers measured in the absence of the test compound, and selecting a test compound which increases the numbers of CD11b<sup>+</sup>CD2<sup>+</sup> macrophages and regulatory CD2<sup>-</sup>CD4<sup>+</sup> T lymphocytes.

For these reasons, the subject matter of Applicant's independent claim 16, as well as newly added, dependent claims 38-43, is clearly patentable over the teachings of Ishibashi et al.

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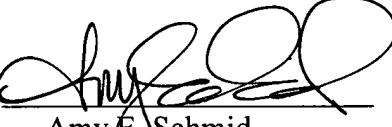
**Conclusion**

Therefore, in view of the foregoing amendments and remarks, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

If, after reviewing this Amendment, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

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